

**REMARKS**

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claims 1-8 are pending in this application. By this Amendment, claim 1 is amended and claims 3 and 5 are cancelled.

Claim 1 is amended to include the feature of claim 3 and to further include that the composition contains isoflavones in an amount of 25-95% by weight of the total solid content. Support for this can be found at page 9, lines 2-6 of the originally filed specification. No new matter is added.

The patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

**I. Double Patenting**

The Examiner has provisionally rejected claims 1-4 and 7 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 and 4 of co-pending U.S. Application No. 10/559,730.

The Examiner has also provisionally rejected claims 5, 6 and 8 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 23 of co-pending U.S. Application No. 10/507,637.

Without admitting to the propriety of the rejections, and in the interest of advancing prosecution, Applicants submit herewith a terminal disclaimer, thus obviating the rejections. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

## II. JP 04266898

The Examiner has rejected claims 1 and 2 under 35 U.S.C. § 102(b) as being anticipated by JP 04266898.

By this Amendment, the feature of claim 3, not subject to this rejection, is incorporated into claim 1. Therefore, the rejection of claim 1 is moot. Claim 2 depends from claim 1 and, thus, also is not anticipated by JP 04266898. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Furthermore, amended claim 1 would not have been rendered obvious by this reference. JP 04266898 relates to the isolation of malonyl glycosides of specific soybean isoflavones, and is totally different from an isoflavone-containing composition having a specific composition of isoflavones and saponins.

Although the Examiner states "due to similarity in extraction of soybean hypocotyls using aqueous ethanol," the composition of the claimed invention cannot be obtained only by the extraction. This is clear from the comparison of Example 1 and Comparative Example 2 that is disclosed in the specification of the present application (hereinafter referred to as the present specification).

That is, in Comparative Example 2, soybean hypocotyls are extracted with 70% aqueous ethanol, the extract is adsorbed on an adsorbent, and then the adsorbed isoflavones and saponins are eluted from the adsorbent with aqueous ethanol having the same concentration as that of the extraction solvent, i.e., 70% aqueous ethanol. This corresponds to the extract of soybean hypocotyls of JP 04266898.

The compositions of the products of Example 1 and Comparative Example 2

calculated based on the relative proportions of isoflavones, total isoflavone content, malonyl isoflavone glycoside content and saponin concentration in Tables 4 and 5 in the present specification are shown in the following table, together with the composition claimed in claim 1.

	Claim 1	Example 1	Comparative Example 2
sum of total amounts of isoflavones and saponins in the composition (a)	100%	72%	53.7%
malonyl isoflavone glycoside content by taking (a) as 100%	15-95%	45.6%	11.2% (outside of claimed scope)
content of isoflavones other than malonyl isoflavone glycoside by taking (a) as 100%	0-50%	21.1%	30.9%
saponin. content by taking (a) as 100%	5-60%	33.3%	61.4% (outside of claimed scope)

As seen from the above table, it is clear that the claimed composition cannot be obtained only by the extraction disclosed in JP 04266898.

In addition, in JP 04266898, the ethanol extract from soybean hypocotyls is subjected to liquid-liquid partition between butanol and water to remove oligosaccharides, and then subjected to LH-20 gel filtration to obtain a crude isoflavone fraction. However, in the gel filtration, elution is carried out with anhydrous methanol (100% methanol) and the eluate is finally

recovered as a 100% methanol solution. Because JP 04266898 is silent on the molecular weight of recovered isoflavones, it can be said that, in JP 04266898, isoflavones are not separated into a specific fraction.

On the other hand, when isoflavones are not separated into a specific fraction, isoflavones and saponins are recovered in the same fraction. Therefore, it is impossible to obtain the claimed composition, which contains a relatively higher amount of malonyl isoflavone glycoside as compared with those of other isoflavones and saponins.

In JP 04266898, the crude isoflavone fraction is further treated by HPLC to isolate the specific malonyl isoflavone glycosides. Thus, it is clear that JP 04266898 is merely directed to the isolation of the specific malonyl isoflavone glycosides, and the claimed composition is not formed during the isolation process thereof. Accordingly, the composition and process disclosed in JP 04266898 would not inherently include the claimed amount of saponins as recited in claim 1.

Thus, claim 1 would not have been rendered obvious by JP 04266898. Claims 2, 4, 6 and 7 depend directly or indirectly from claim 1 and, thus, also would not have been rendered obvious by JP 04266898.

### **III. Bombardelli et al., Matsuura et al. and Shiraiwa et al.**

The Examiner rejects claims 1-8 under 35 U.S.C. § 103(a) as being unpatentable over Bombardelli et al. (U.S. Patent No. 7,108,871) taken together with Matsuura et al. (U.S. Patent No. 5,789,581) and Shiraiwa et al. (Composition and Structure of "Group A Saponin" in Soybean Seed, Agric. Biol. Chem. (1991)). By this Amendment claims 3 and 5 are cancelled,

rendering their rejection moot. As for the remaining claims, Applicants respectfully traverse the rejection.

The references relied upon by the Examiner do not teach or suggest the claimed invention. The isoflavone content in the claimed composition is limited to 25 to 95% by weight of the total solid content. Thus, the claimed composition is clearly distinguished from the composition of Bombardelli et al. because the isoflavone content of the composition of Bombardelli et al. is 13 to 17% (see column 6, lines 32-33). Further, the proportion of group A saponins has been limited by incorporating claim 3 into claim 1 to exclude the use of whole soybeans as a starting material.

**A. Bombardelli et al.**

Bombardelli et al. disclose an isoflavone-containing composition. In brief, the composition of Bombardelli et al. is produced by the following steps:

- a) extraction of a soybeans starting material with aqueous ethanol (to extract isoflavones and saponins);
- b) treatment of the extract with hexane (removal of fat components);
- c) partition between butanol and, water (concentration of isoflavones and saponins);
- d) adsorption with adsorbent and washing with water (removal of salts and other inactive components); and
- e) elution with ethanol (elution of adsorbed isoflavones and saponins).

See Bombardelli et al. at column 11, lines 35-49.

Although the Examiner states that Bombardelli et al. exemplify the ethanol extraction inherently at room temperature (page 4, paragraph 6 of the Official Action), Bombardelli et al,

recommend to carry out the ethanol extraction with heating at 55°C or higher (column 7, line 15). Further, in Example 1 of Bombardelli et al., which is the only Example disclosing the extraction, the extraction is carried out under reflux. In view of the disclosed solvent, the refluxing is usually carried out by heating at about 70°C.

However, as disclosed at page 15, lines 19-24 of the present specification, when the extraction temperature exceeds 50°C, malonyl isoflavone glycosides are thermally decomposed and converted into free isoflavone glycosides, which results in the lowering of malonyl isoflavone glycoside content (see Tables 4 and 5 of the present specification).

In addition, the Examiner refers to the combination of absorption and elution steps. However, the adsorption is carried out only for removal of salts and other inactive components, and the adsorbent is finally eluted with high concentration ethanol to elute all the isoflavones and saponins. Therefore, the proportion of isoflavones and saponins are unchanged before and after the adsorption treatment (column 6, line 30 and column 12, lines 1-3). That is, Bombardelli et al. do not teach or suggest the absorption of the claimed invention for producing an isoflavone-containing composition having a specific composition of isoflavones and saponins.

In view of the above, it is clear that Bombardelli et al. would not have motivated a person skilled in the art to have prepared an isoflavone-containing composition that is highly soluble in water and has high purity.

**B. Matsuura et al.**

Matsuura et al. disclose the preparation of malonyl isoflavone glycosides. In Matsuura et al., it is essential to extract soybeans at first with water to selectively extract malonyl isoflavone glycosides (see column 2, lines 46-47). However, when soybeans are extracted with water, not

aqueous alcohol, malonyl isoflavone glycosides are decomposed by (3-glucosidase soybeans into aglycones, which results in the lowering of the malonyl isoflavone glycoside content). This is shown by Table 3, 10% aqueous ethanol of the present specification.

Even if the extraction with aqueous ethanol under reflux of Bombardelli et al. is replaced with the extraction with water of Matsuura et al., the claimed isoflavone-containing composition, which is highly soluble in water and has high purity, cannot be obtained. Accordingly, it would have taken more than routine experimentation to have arrived at the claimed invention.

**C. Shiraiwa et al.**

Shiraiwa et al. disclose group A saponins and the extraction thereof from soybean hypocotyls. However, Shiraiwa et al. do not teach or suggest the specific proportion of group A saponins of the claimed composition. Further, the extraction is carried out under reflux at 80°C (see page 316, right column). Therefore, as with Bombardelli et al., malonyl isoflavone glycosides are decomposed and the desired composition having 15 to 95% by weight of malonyl isoflavones glycosides could not be obtained. Accordingly, the techniques disclosed in Bombardelli et al. and Shiraiwa et al. would not have led to the claimed invention. Therefore, even if Shiraiwa et al. were combined with Bombardelli et al., the combination does not teach or suggest the claimed invention.

Therefore, claim 1 would not have been rendered obvious by Bombardelli et al., taken together with Matsuura et al. and Shiraiwa et al. Claims 2, 4, 6 and 7 depend directly or indirectly from claim 1 and, thus, also would not have been rendered obvious by these references. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

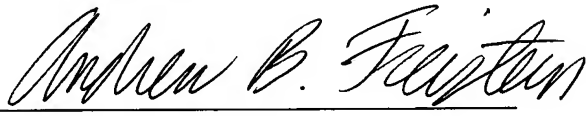
**IV. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 2, 4, and 6-8 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place the application in better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

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Enclosure:

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